

UNITED STATES PATENT AND TRADEMARK OFFICE

PARTMENT OF COMMERCE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/617,217	07/11/2003	Akio Matsuda	1254-0229P	6837	
2292	7590 01/04/2006		EXAMINER		
	EWART KOLASCH &	BORIN, MICHAEL L			
PO BOX 747 FALLS CHURCH、VA 22040-0747			ART UNIT	PAPER NUMBER	
	,	1631			
				DATE MAIL ED. 01/04/2006	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/617,217	MATSUDA ET AL.
Office Action Summary	Examiner	Art Unit
	Michael Borin	1631
The MAILING DATE of this communication apprehension for Reply	ears on the cover sheet with the c	orrespondence address
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period who are to reply within the set or extended period for reply will, by statute, any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONED	l. ely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
Responsive to communication(s) filed on 10 Au This action is FINAL. 2b) ☐ This Since this application is in condition for allowant closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro	
Disposition of Claims		
4) ☐ Claim(s) 1-45 is/are pending in the application. 4a) Of the above claim(s) 1,2,8,12,14-45 is/are 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	withdrawn from consideration.	
Application Papers		
 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the 	epted or b) \square objected to by the E	
Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Ex	, -, ,	•
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

Art Unit: 1631

DETAILED ACTION

Status of Claims

- 1. Claims 1-45 are pending.
- 2. Response to restriction requirement filed 08/10/2005 is acknowledged. Applicant elected, with traverse, Group II, claims 3-7,9-11,13 and nucleic acid SEQ ID No. 88. Applicant argues that claims of Group XIX are directed to nucleic acid comprising a fragment of SEQ ID No. 88. However, such nucleic acid have different function (inhibition of protein expression) and different structure (containing sequence "corresponding" to a part of a polynucleotide of claim 3), and a reference teaching polynucleotide SEQ ID No. 88 will not teach or suggest polynucleotide of claim 23. Similarly, a reference teaching polynucleotide SEQ ID No. 88 will not teach or suggest products of claim 25. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 1,2,8,12,14-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 1,2,8,12,14-45 and amendment of claims 3-7,9-11,13 to read on elected invention are requested.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, page 3,4. Applicant is requested to delete the embedded hyperlinks and/or other form of browser-executable codes in the specification. See MPEP § 608.01(b).

Art Unit: 1631

Claim Rejections - 35 U.S.C. § 101/112-1

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Page 3

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility. "Specific" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

- A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.
- B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)
- C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".
- D. A method of making a material that itself has no specific, substantial, and credible utility.

Page 4

Application/Control Number: 10/617,217

Art Unit: 1631

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

4. Claims 3-7,9-11,13 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The invention is drawn to isolated nucleic acids comprising sequence SEQ ID No. 88 or analogs thereof.

Utility of a polynucleotide is defined either by the utility of the polynucleotide itself or by utility of polypeptide it encodes. Specification addresses polypeptide SEQ ID No. 88 as having (an unidentified) homology to Toll/IL-1 receptor domain sequence, and as being localized in a number of tissues(p. 47). Further, the intracellular localization of protein SEQ ID No. 87 is addressed (p. 67). Identifying a polypeptide as having a limited homology to the claimed polypeptides does not indicate what function it might have. Assignment to a prior art family of polypeptides is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the polypeptide family. Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) disclose that the skilled artisan is well aware

Application/Control Number: 10/617,217

Art Unit: 1631

that assigning functional activities for any particular polypeptide or polypeptide family based upon sequence homology is inaccurate, in part because of the multifunctional nature of polypeptides (see, e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two polypeptides, only experimental research can confirm the artisan's best guess as to the function of the structurally related polypeptide (see in particular "Abstract" and Box 2). Thus, the homology-based assignment of the claimed polypeptide does not appear to provide evidence of a specific and substantial utility based on the knowledge of the skilled artisan and the data presented in the instant specification.

It is also said that that polypeptide SEQ ID No. 87 is expressed in various tissues including leukocytes, spleen, lung and uterus (p. 47). However, there is no nexus to any particular disease or condition that would demonstrate the utility of identifying said polypeptide in these tissues. After further research, specific and substantial utility might be found for claimed polypeptide. This further characterization, however is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. As such, further research would be required. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), the court indicates "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent is therefore not a license to experiment. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed. The basic

Application/Control Number: 10/617,217 Page 6

Art Unit: 1631

<u>quid pro quo</u> of the patent system, as interpreted by the <u>Brenner</u> Court, is the grant of a valuable legal right in exchange for a meaningful disclosure of the claimed invention.

Further, even if the nucleotide of SEQ ID No. 88 had a demonstrated utility, there is no specific or substantial utility either for its fragments or for its homologs because no structural requirements for [a presumed] utility of these fragments or homologs are identified.

The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

5. Claims 3-7,9-11,13 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

Application/Control Number: 10/617,217 Page 7

Art Unit: 1631

only if the international application designated the United States and was published under Article 21(2)

of such treaty in the English language.

6. Claims 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by the sequence SEQ ID No. 15 of US 200030012966. The referenced sequence shows 99% similarity to SEQ ID No. 88 of the instant invention (see attached sequence alignment). Therefore, the referenced polynucleotide reads on the polynucleotides of claims 3-6 which have at least one substitution in SEQ ID No. 88. Further, as the referenced sequence has continuous stretches matching the claimed sequence of SEQ ID No. 88, it would be expected to hybridize to SEQ ID No. 88 under high stringency conditions absent evidence to the contrary.

Conclusion.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D. Primary Examiner

Art Unit 1631

mlb